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09/890,167	07/27/2001	Nancy L. Paiva	11137/04704	7718

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/890,167	PAIVA ET AL.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 November 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) 31-33 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-30 and 34-42 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-30 and 34-42 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 31-33 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.
3. This application contains claims 31-33 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144). See MPEP § 821.01.

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 371 and 119 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR § 1.78(a)(2) and (a)(5)).

Information Disclosure Statement

5. The information disclosure statement filed 11 December 2001 has been considered, a signed copy is attached hereto.

Drawings

6. The Draftsman has approved the drawings filed 27 July 2001.

Claim Objections

7. Claims 19 and 20 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 19 and 20 are objected to because the limitation "said resveratrol synthase transgene comprises at least one recombinant DNA sequence" does not appear to further limit the claim upon which the claim is dependent. In the instant case, a transgene inherently comprises a recombinant DNA sequence.

8. Claims 24-26 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon any other multiply dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-30 and 34-42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 1, 15, 29, 27 and 39, the limitation "at the time of consumption" is indefinite because it is unclear what the metes and bounds of the limitation are. In the

instant case the plant has been transformed with a transgene under the control of a constitutive promoter which promotes expression of a transgene constitutively, hence the transgenic plant cells would always be producing resveratrol synthase, hence would always exhibit an increased concentration of resveratrol glucoside. This appears to be an intended use limitation.

Claims 3, 4, 10, 11, 17, 18, 28, 30, 35, 40 and 42 are indefinite because the phrases; "said resveratrol synthase transgene is SEQ ID NO: 2" at claims 3, 4, 10, 11, 17 and 18, and "said open reading frame is SEQ ID NO: 2" at claims 28, 30, 35, 40 and 40, refer to a "transgene" or "open reading frame" which denotes a nucleic acid sequence, while the sequence of SEQ ID NO: 2 is an amino acid sequence. Amending the claims to read -- encodes the amino acid sequence of SEQ ID NO: 2 -- would obviate this rejection.

At claims 27, 34 and 41, the limitation "under conditions conductive to the accumulation..." is indefinite because it is unclear what the metes and bounds of this limitation are. In the instant case, it is unclear what the conditions are if it is not inherent in the fact that the plant cells are transformed to constitutively express a resveratrol synthase transgene.

Claim 29 is indefinite because the claim does not set forth any positive method steps by which one of skill in the art is to practice the claimed method. Hence, it is unclear what the metes and bounds of the claim are.

At claim 34, lines 6-8, the limitation "cultivating...under conditions to..the suppression of β -glucosidases" is indefinite because it is unclear what the metes and

bounds of such conditions are. The specification at page 18, lines 12-15 does not sufficiently teach what the metes and bounds of the cultivating conditions are that would produce the “suppression” as claimed. In fact, the suggestion of the specification is that the “suppression of β -glucosidases” is inherent in transforming a plant with a resveratrol synthase open reading frame under expression control of a constitutive promoter.

Those claims not specifically mentioned in this rejection are rejected as indefinite for being dependent upon an indefinite claim, and do not obviate the indefiniteness of the claim(s) upon which they depend.

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 3-7, 10-14, 17, 18, 21-26, 28, 30, 35-38, 40 and 42 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims transformed plant material, compositions comprising said transformed plant material, transformed plants and a method of using said transformed plants comprising a transgene encoding the amino acid sequence of SEQ ID NO: 2.

Applicant teaches that Applicant transformed plants with a cDNA encoding the peanut RS3 gene taught by Tropf *et al* (1994, *J. Mol. Evol.* 38:610-618) (page 20, lines 18-21 of the specification).

Tropf teaches that the N-terminal amino acid sequence of the peanut RS3 protein comprises the amino acid sequence MVSVSGIRK-, while Applicant teaches that the peanut RS3 gene, in SEQ ID NO: 1 and 2, comprises the amino acid sequence MEGGIRK- (see Figure 5A on page 615 of Tropf). Hence, it is unclear from the instant specification that Applicant has enabled the instant claims. It is unclear why there is a difference between the teachings of the amino acid sequence of the peanut RS3 protein of Tropf and the teachings of Applicant in the instant case.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 2, 5-9, 12-16, 19-27, 29, 34, 36-39 and 41 rejected under 35 U.S.C. § 103(a) as being unpatentable over Schroder *et al* (U.S. Patent 5,689,046 issued 18 November 1997) in view of Comai *et al* (U.S. Patent 5,106,739).

The indefiniteness of claim 34 is discussed *supra*.

Schroder teaches a method of producing a transgenic plant comprising a resveratrol synthase transgene and transformed plants (see claim 13 and columns 18-23). Schroder teaches a method of producing a transgenic alfalfa plant comprising said transgene (see column 14 at line 48). Schroder teaches that it is desirable to transform a soybean plant with the taught transgene (see column 6, line 16). Schroder teaches that other promoter sequences, other than the promoter sequence native to the taught

resveratrol synthase gene, can be operably linked to the taught coding sequence (see column 2, lines 30-35, and column 4, lines 19-31). Schroder teaches that plants transformed with the taught transgene have increased resistance to fungal and bacterial pathogens and spoilage inducing organisms (see column 5).

Schroder does not specifically teach operably linking the taught resveratrol synthase coding sequence to a constitutive promoter.

Comai teaches a CAMV 35S enhanced MAS promoter that is constitutive and functional in transgenic plants (see claim 15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's inventions to use the teachings of Comai to use the constitutive enhanced MAS promoter to modify the teachings of Schroder to constitutively express a resveratrol synthase transgene in a transgenic plant, including alfalfa or soybean as suggested by Schroder. Given the success of Schroder in expressing the taught resveratrol synthase transgene in alfalfa, tobacco and potato, one of ordinary skill in the art would have had a reasonable expectation of success in modifying the teachings of Schroder to constitutively express the taught resveratrol synthase transgene in a transgenic plant. Schroder clearly teaches that other plant functional promoters known in the art can be used to express the coding sequence of the taught resveratrol synthase enzyme.

The claimed "edible plant material" is considered an intended use limitation in the instant claims. In addition, the claimed composition comprising the claimed edible plant material would have been obvious to one of ordinary skill in the art at the time of

Applicant's invention given that Schroder motivates one of ordinary skill in the art to transform plants commonly used as human and animal food products such as alfalfa and soybean as discussed *supra*. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

15. Claims 1, 2, 5-9, 12-16, 19-27, 29, 34, 36-39 and 41 rejected under 35 U.S.C. § 103(a) as being unpatentable over Hain *et al* (U.S. Patent 5,689,047 issued 18 November 1997) in view of Comai *et al* (U.S. Patent 5,106,739).

The indefiniteness of claim 34 is discussed *supra*.

Hain teaches a method of producing a transgenic plant comprising a resveratrol synthase transgene and transformed plants (see claim 8 and columns 11-15). Hain teaches that it is desirable to transform a soybean or an alfalfa plant with the taught transgene (see column 7, line 43). Hain teaches that other promoter sequences, other than the promoter sequence native to the taught resveratrol synthase gene, can be operably linked to the taught coding sequence (paragraph spanning columns 3-4). Hain teaches that plants transformed with the taught transgene have increased resistance to fungal and bacterial pathogens and spoilage inducing organisms (see columns 8-9).

Hain does not specifically teach operably linking the taught resveratrol synthase coding sequence to a constitutive promoter.

Comai teaches a CAMV 35S enhanced MAS promoter that is constitutive and functional in transgenic plants (see claim 15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's inventions to use the teachings of Comai to use the constitutive enhanced MAS promoter to modify the teachings of Hain to constitutively express a resveratrol synthase transgene in a transgenic plant, including alfalfa or soybean as suggested by Hain. Given the success of Hain in expressing the taught resveratrol synthase transgene in tobacco and potato, one of ordinary skill in the art would have had a reasonable expectation of success in modifying the teachings of Hain to constitutively express the taught resveratrol synthase transgene in a transgenic plant. Hain clearly teaches that other plant functional promoters known in the art can be used to express the coding sequence of the taught resveratrol synthase enzyme.

The claimed "edible plant material" is considered an intended use limitation in the instant claims. In addition, the claimed composition comprising the claimed edible plant material would have been obvious to one of ordinary skill in the art at the time of Applicant's invention given that Hain motivates one of ordinary skill in the art to transform plants commonly used as human and animal food products such as alfalfa and soybean as discussed supra. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the

prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

16. Claims 3, 4, 10, 11, 17, 18, 28, 30, 35, 40 and 42 appear to be free of the prior art which does not appear to teach or suggest the amino acid sequence shown in SEQ ID NO: 2 encoding a resveratrol synthase enzyme. This is the *prima facie* assumption by the Examiner because of the issue outlined in the rejection above under 35 USC 112, first paragraph.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



David H. Kruse, Ph.D.
6 January 2003

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